

REMARKS

Applicants respectfully requests entry of the amendments and remarks submitted herein. Applicants thank the Examiner for the telephone conference of February 11, 2004. Claims 37, 39, 41, 43, 54, 56, 58, and 60 have been amended as described below. Reconsideration of the pending application is respectfully requested.

The 35 U.S.C. §103 Rejections

Claims 37-50, 68-75, and 79 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Davison et al. (*J. Gen. Virol.*, 1986) in view of Rose et al. (U.S. Patent No. 5,925,733) and in further view of Wittwer et al. (U.S. Patent No. 6,174,670). This rejection is respectfully traversed.

The Examiner asserted that the Davison et al. reference teaches the complete DNA sequence of VZV including genes 28 and 29 and SEQ ID NOs:1-8. The Examiner also asserted that the Rose et al. reference teaches specific gene 28 primers and probes used in a PCR-based detection assay using fluorescently-labeled probes, and that altering the number of amplification cycles to obtain the desired fragment is a routine matter for a practitioner of ordinary skill in the art. The Examiner further asserted that the Wittwer et al. reference teaches a method of PCR amplification for the detection of viral polynucleotides. The Examiner concluded, therefore, that it would have been obvious to one of ordinary skill in the art at the time the invention was made to detect the sequences of Davison et al. through the PCR method of Rose et al. in view of Wittwer et al.

As discussed with the Examiner in the above-indicated February 11, 2004 telephone conference, claims 37, 39, 41, 43, 54, 56, 58, and 60 have been amended to recite that the specific primer or probe is "no more than 30 nucleotides in length and comprises the sequence...." Applicants do not acquiesce to the Examiner's reasons for maintaining the rejection, but have made these amendments to expedite prosecution. Support for the amendments can be found, for example, on page 7, lines 5 and 21-22. Applicants note that nucleotides present in a primer or probe in addition to a recited sequence can be VZV gene 28 or

29 sequences, or they can be non-VZV sequences (see, for example, the specification at page 6, line 19 through page 8, line 16).

Alone or in combination, the Davison et al. reference, the Rose et al. reference, and/or the Wittwer et al. reference do not teach or suggest a primer or probe comprising the particular recited sequence and having a length of 30 or fewer nucleotides. Applicants submit that in view of the length limitation now recited, the claims as amended recite very specific primer and probe sequences. In view of the claim amendments and remarks herein, Applicants respectfully request that the rejection of claims 37-50, 68-75, and 79 under 35 U.S.C. §103(a) be withdrawn.

Claims 37-75 and 79 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Davison et al. in view of Rose et al., in further view of Wittwer et al., and in further view of Beards et al. (*J. Med. Virol.*, 1998). Applicants respectfully traverse this rejection.

The Examiner indicated that the combined teachings of Davison, Rose, and Wittwer do not teach gene 29 specific primers and probes with which to practice the claimed method. The Examiner indicated, however, that the Beards et al. reference teaches 4 sets of specific primers for gene 29 and VZV detection. The Examiner concluded, therefore, that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have supplemented the teachings of Davison, Rose, and Wittwer with the primers/probes specific for gene 29 as taught by the Beards et al. reference.

As indicated above, independent claims 37, 39, 41, 43, 54, 56, 58, and 60 have been amended to recite that the specific primer or probe is "no more than 30 nucleotides in length and comprises the sequence...." In view of the length limitation now recited, the claims as amended are directed toward very specific primer and probe sequences. Alone or in combination, the Davison et al. reference, the Rose et al. reference, the Wittwer et al. reference, and/or the Beards et al. reference do not teach or suggest a primer or probe comprising the particular recited sequence and having a length of 30 or fewer nucleotides. In view of the claim amendments and remarks herein, Applicants respectfully request that the rejection of claims 37-75 and 79 under 35 U.S.C. §103(a) be withdrawn.

Claims 76-78 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Davison et al. in view of Rose et al. and Wittwer et al. and in further view of Longo et al. This rejection is respectfully traversed.

The Examiner asserted that the combined teachings of Davison, Rose, and Wittwer do not teach steps involving preventing amplification of a contaminant nucleic acid. The Examiner asserted, however, that the Longo et al. reference teaches the step of preventing amplification of a contaminant nucleic acid by performing the amplifying step in the presence of uracil and treating the biological sample with uracil-DNA glycosylase prior to the first amplifying step. The Examiner concluded, therefore, that it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the steps of Longo et al. in order to reduce the chance of contamination and, thereby, the chance of obtaining false positives.

As indicated above, independent claims 37, 39, 41, 43, 54, 56, 58, and 60 have been amended to recite that the specific primer or probe is "no more than 30 nucleotides in length and comprises the sequence...." In view of the length limitation now recited, the claims as amended are directed toward very specific primer and probe sequences. Alone or in combination, the Davison et al. reference, the Rose et al. reference, the Wittwer et al. reference, and/or the Longo et al. reference do not teach or suggest a primer or probe comprising the particular recited sequence and having a length of 30 or fewer nucleotides. In view of the claim amendments and remarks herein, Applicants respectfully request that the rejection of claims 76-78 under 35 U.S.C. §103(a) be withdrawn.

Claim 79 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Davison et al. in view of Rose et al. in further view of Wittwer et al. and further in view of Sauerbrei et al. (*J. Clin. Virol.*, 1999). Applicants respectfully traverse this rejection.

The Examiner asserted that the combined teachings of Davison, Rose, and Wittwer do not teach a step in which the biological sample is selected from the group of samples recited in pending claim 79. The Examiner asserted, however, that the Sauerbrei et al. reference teach virological diagnosis of VZV in vesicle fluid, swabs from the dermatomes of the chest, head, neck, waist, and pelvis, as well as serum samples. The Examiner concluded, therefore, that it would have been obvious to one of ordinary skill in the art at the time the invention was made to

have practiced the FRET-based viral detection method of Wittwer using PCR with primers of genes 28 and 29 as the method of choice for rapid diagnosis of VZV since the genomic sequence of VZV is taught by the Davison et al. reference, the detection of biological samples is taught by the Rose et al. reference, and similar primers for genes 28 and 29 are taught by the Sauerbrei et al. reference.

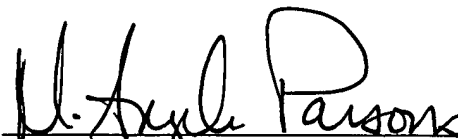
As indicated above, independent claims 37, 39, 41, 43, 54, 56, 58, and 60 have been amended to recite that the specific primer or probe is "no more than 30 nucleotides in length and comprises the sequence...." In view of the length limitation now recited, the claims as amended are directed toward very specific primer and probe sequences. Alone or in combination, the Davison et al. reference, the Rose et al. reference, the Wittwer et al. reference, and/or the Sauerbrei et al. reference do not teach or suggest a primer or probe comprising the particular recited sequence and having a length of 30 or fewer nucleotides. In view of the claim amendments and remarks herein, Applicants respectfully request that the rejection of claim 79 under 35 U.S.C. §103(a) be withdrawn.

CONCLUSION

Applicants respectfully request that claims 37-79 be allowed. Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: February 17, 2004


M. Angela Parsons, Ph.D.
Reg. No. 44,282

Fish & Richardson P.C., P.A.
60 South Sixth Street
Suite 3300
Minneapolis, MN 55402
Telephone: (612) 335-5070
Facsimile: (612) 288-9696